

Patent Application of Joar Opheim  
Flavored Gelatin Capsule and Method of Manufacture

This application is a continuation of my co-pending application 09/416,017 filed on October 6, 1999, and the entire disclosure thereof is hereby incorporated herein by reference.

## BACKGROUND OF THE INVENTION

## 10 1. Field of the Invention

12 This invention relates to capsule formulations, medicinal and nutritive  
13 dose encapsulations and methods of manufacture of capsules. More  
14 specifically, the invention introduces flavoring into the manufacture of  
15 capsules and encapsulated doses.

## 17 2. Conventional Art

19 The taste of many medicinal and nutritive components can be quite  
20 distinctive and potentially unpleasant. Improvements in the taste of certain  
21 drugs and nutritional supplements can lead to a higher compliance by  
22 consumers. A higher compliance will result in greater commercial success  
23 for the drug and supplement manufacture and in increased health and well  
24 being particular consumers.

25       Taste is both a matter of purely subjective preference. Yet human taste  
26   is also strongly influenced by experience and cultural impressions. Broad  
27   generalizations about consumer taste presence can thus sometimes be relied  
28   upon in predicting market acceptance of specific drug and nutritive  
29   formulations. In Norway, for example the tastes of fish oils are far more  
30   palatable than in the United States. As a consequence of this United States  
31   market aversion to the taste of fish oils, many residents of the United States  
32   are less willing to ingest fish oils and will therefore not benefit from the  
33   nutritional and medicinal qualities of fish oils.  
34

35 Yet the composition of certain fish oils includes elements that are  
36

1 identified in medical literature as providing significant health benefits.  
2 Polyunsaturated fatty acids, to include long chain Omega 3 fatty acids such  
3 as eicosapentenoic acid (EPA) and docosahexenoic acid (DHA) are present  
4 in the livers of lean fish and other tissues of  
5 fatty fish. The human body cannot synthesize these fatty acids nor can it  
6 derive them from other fatty acids. As these fatty acids provide both  
7 medicinal and nutritional benefits, an intake of up two grams per day has  
8 been recommended by certain medical authorities.

9  
10 It is suspected that Eicosanoids derived from EPA might have an anti-  
11 inflammatory effect on humans. It has been suggested that EPA might  
12 decrease blood levels of TG lipids, increase blood levels of high density  
13 lipids (HDL), decrease blood clotting, reduce the incidence of cardiac  
14 arrhythmia and stabilize heart rhythm.

15  
16 It has been suggested that DHA may also decrease blood levels of TG  
17 lipids, increases blood levels of high density lipids (HDL). Furthermore,  
18 DHA might lower blood pressure, attack early phases of inflammation,  
19 facilitate the growth, development and function of the central nervous  
20 system and improves the clinical symptoms of depression and  
21 schizophrenia.

22  
23 Increasing the consumption of recommended doses of certain Omega-  
24 3 fatty acids might therefore have a medically and nutritionally beneficial  
25 affect on many consumers and patients. Yet conventional techniques to  
26 improve the palatability of fish oils and other subjectively harsh tasting  
27 substances are limited in the prior art to the addition of flavorings into a  
28 mixture of the substances themselves. The flavoring of capsules of  
29 encapsulated formulations has been absent in the conventional art.

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31 **OBJECTS OF THE INVENTION**  
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33 It is therefore an object of the present invention to provide a method of  
34 manufacture of gelatin capsules.

35 It is another object of the present invention to provide a gelatin  
36 capsule comprising a flavor.

1 It is an additional object of the present invention to optionally provide  
2 a flavored gelatin capsule containing a fish oil.

3 It is an yet another object of the present invention to optionally  
4 provide a flavored gelatin capsule containing a flavored fish oil.

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6

7 **SUMMARY OF THE INVENTION**

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9 These and other objects and advantages of the present invention are  
10 achieved by providing a flavored gelatin capsule comprising a water soluble  
11 flavor. The flavored gelatin capsule may include about 10 to about 70 parts  
12 by weight of a gelatin, about 10 to about 35 parts by weight of a glycerol,  
13 about 8 to about 35 parts by weight of a moisturizer and about 1 parts by  
14 weight of the water soluble flavoring. The flavoring of the capsule improves  
15 the taste and palatability of the capsule and will subjectively improve the  
16 taste of the gelatin and a dose or contents contained within the flavored  
17 gelatin capsule to individual consumers or patients.

18

19 The flavor may be one of, or a combination of suitable flavors known  
20 in the art, to include berry, strawberry, chocolate, cocoa, vanilla, lemon, nut,  
21 almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry,  
22 peach, lemon, lime, mint, peppermint, orange, banana, chili pepper, pepper,  
23 cinnamon, and pineapple.

24

25 The gelatin capsule composition may include a polyol, such as  
26 sorbitol, glycerol or other suitable softening agent known in the art.

27

28 A preferred embodiment of the present invention includes flavoring  
29 the contents of the gelatin capsule in addition to flavoring the gelatin  
30 capsule. In particular, an oil soluble flavoring may be optionally mixed with  
31 a fish oil that is encapsulated within the capsule. The oil soluble flavoring  
32 may be similar to the taste of the flavor of the capsule, e.g., strawberry and  
33 strawberry, or the taste of the oil flavoring may be complementary to the  
34 capsule flavoring, e.g., banana and strawberry.

35

36 Fish oil containing Omega 3 fatty acids such as eicosapentenoic acid

1 (EPA) and docosahexenoic acid (DHA) are one appropriate subject of  
2 inclusion into certain preferred embodiments of the present invention. The  
3 capsule of these certain preferred embodiments is flavored and the fish oil  
4 may optionally be flavored.

5  
6 The method of the present invention includes the manufacturing  
7 process steps of combining gelatin, a glycerol or a polyol like sorbitol as a  
8 softener, water or a moisturizer containing water, a flavoring agent and  
9 optionally a coloring agent such as a titanium oxide, keratin or other suitable  
10 coloring agent known in the art.

11  
12 Modified vegetable starch is substituted for gelatin in certain preferred  
13 embodiments of the present invention. Where gelatin is used, the gelatin  
14 may be a suitable mammalian or fish gelatin known in the art. The suitable  
15 gelatin or vegetable starch selected is used as a principal forming agent of  
16 the capsule.

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19 BRIEF DESCRIPTION OF DRAWINGS

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21 FIG. 1 is a flavored gelatin capsule containing a fish oil dose.

22 FIG. 2 is manufacturing process flow chart illustrating an embodiment  
23 of the method of the present invention.

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25  
26 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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28 In describing the preferred embodiments, certain terminology will be  
29 utilized for the sake of clarity. Such terminology is intended to encompass  
30 the recited embodiment, as well as all technical equivalents which operate in  
31 a similar manner for a similar purpose to achieve a similar result.

32  
33 Referring now to Figure 1, an encapsulated composition of a gelatin  
34 capsule and fish oil 2, or fish oil capsule 2, is formed by the encapsulation of  
35 a dose of fish oil 6 by a gelatin capsule 4. The gelatin capsule 4 is made of  
36 gelatin, glycerol, water, a flavoring and optionally a coloring agent. The fish

1 oil dose 6 includes 180 mg of EPA and 120 mg of DHA.

2  
3 Referring now to Figure 1 and 2, the manufacturing process of the  
4 preferred embodiment 2 of includes the steps of combining gelwatch  
5 ingredients, melting and forming a liquefied gelwatch, delivering the  
6 liquefied gelwatch and the fish oil 6 to an encapsulation machine,  
7 encapsulating a dose of fish oil, drying the encapsulated dose, washing the  
8 encapsulated dose and packaging the fish oil capsules 2 for shipment.

9  
10 The gelwatch ingredients may include gelatin or a gelatin substitute  
11 such as modified starch or other suitable gelatin substitute known in the art,  
12 a softener such as glycerol or sorbitol or other suitable polyol or other gelatin  
13 softener known in the art, a flavoring agent such as strawberry flavor  
14 Firmenich #52311A or other suitable gelatin capsule flavoring known in the  
15 art and optionally a coloring agent such as keratin or other suitable gelatin  
16 capsule coloring agent known in the art.

17  
18 The preferred embodiment 2 may be formed from a gelwatch mixture  
19 of 45 parts by weight of gelatin, 20 parts by weight of glycerol, 35 parts by  
20 weight of water and 0.5 or more parts by weight of strawberry flavor  
21 Firmenich #52311A. The gelwatch ingredients are then heated to about 60  
22 degrees to 70 degrees Celsius and mixed together. The capsule is made of  
23 the gelwatch material. The liquefied gelwatch and the fish oil 6 is then  
24 poured into an encapsulation machine. The encapsulation machine then  
25 forms the fish oil capsule 2 comprising the fish oil dose 6 encapsulated by  
26 the gelatin capsule 4.

27  
28 In certain alternate preferred embodiments of the present invention the  
29 range of water parts initially combined with the gelwatch may range from  
30 about 10 parts by weight to about 45 parts by weight; the amount of gelatin  
31 initially combined into the gelwatch may range from 10 parts by weight to  
32 about 70 parts by weight; and the amount of glycerol or other suitable  
33 softener known in the art may range from about 10 parts by weight to about  
34 35 parts by weight.

35  
36 The capsule composition 2 comprises about 500 milligrams of the fish

1 oil dose 6 and about 240 milligrams of capsule 4 as formed from the  
2 gelswatch.

3

4 The fish oil capsule composition 2 is then dried at a temperature of  
5 about 20 degrees Celsius. The water content of the gelatin capsule is  
6 reduced to about 8% +/- 2% by evaporation during the drying process step.  
7 The capsule 2 is then washed and packaged for shipment.

8

9 Experimental testing of the effects of varying amounts of the flavoring  
10 in both the capsule 4 and the fish oil 6 has shown that a concentration of  
11 0.5% in the fish oil 6 of the Firmenlch #52311A flavor will degrade in less  
12 than a year's span to below a desirable level of potency to the average North  
13 American consumer. Levels of 1 part by weight are preferred in order to  
14 extend the effective shelf life of the composition 2 beyond one year.

15

16 In addition, stream of commerce testing of concentration levels of  
17 Firmenich #52311A has shown that a level in excess of about 1.0 part by  
18 weight of the Firmenich #52311A in the capsule 4 provides an unexpected  
19 increase in the palatability of the composition 2 by generating a flavored  
20 bouquet from the capsules 2, whereby the consumer is greatly encouraged to  
21 ingest the composition 4 in a favorable response to his or her olfactory  
22 appreciation of the bouquet.

23

24 Certain preferred embodiments comprise fish oil presenting  
25 concentrations of Omega 3 fish as high or higher than 80% of the total  
26 weight of the dose 6, wherein the fish oil may include 50% DHA of the total  
27 weight of the dose 6, 20% EPA of the total weight of the dose 6 and about  
28 10% by weight of other Omega 3 compounds. The concentration levels of  
29 the flavoring additive of a fish oil dose may, in certain preferred  
30 embodiments of the present invention having about 80% by weight of  
31 Omega 3 components, is reduced to from about 0.25% by weight to about  
32 0.50% by weight of the dose 6

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34 Those skilled in the art will appreciate that various adaptations and  
35 modifications of the just-described preferred embodiments can be  
36 configured without departing from the scope and spirit of the invention.

1 Therefore, it is to be understood that, within the scope of the appended  
2 claims, the invention may be practiced other than as specifically described  
3 herein.